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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,707	02/26/2002	Gregory G. Brucker	S63.2-10308	1518

490 7590 10/26/2004

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

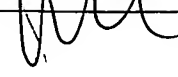
HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/083,707	Applicant(s) BRUCKER ET AL. 	
	Examiner (Jackie) Tan-Uyen T. Ho	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19, 21 and 35-40 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19, 21 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 17-19, 21, and 35-40 are objected to because of the following informalities: The preamble should be "An apparatus comprising" instead of "a system for deploying a bifurcated stent assembly." Since all claims direct to combination of the system for deploying a stent assembly and the stent assembly. The phrase "characterized as" should be removed from the claims. Appropriate correction is required.

Response to Amendment

2. The amendment filed 8/3/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a system for deploying a bifurcated stent assembly with only a single catheter having only a single balloon. The original specification discloses the system for deploying a bifurcated stent assembly including first and second catheter or a single catheter with dual balloon (not a single balloon).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17-19, 21, 35-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification fails to disclose a single catheter having a single balloon for delivering a bifurcated stent assembly.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 17-19, 21, 35-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear whether a first and second stent bodies are included in the system or excluded from the system since claim 17 cites "the system comprising only a single catheter, the single catheter having only a single balloon;"

7. Regarding to the new matter and indefinite as indicated above, the claims are rejected both way 35 USC 102 and 103 (see below).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 17-19, 21 and 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Vardi et al. (6,325,826).

Vardi et al. disclose two single catheters, each with a single balloon (24, 25) and the stent having structure and being made from material as claimed wherein the stent includes a first stent body (40, 100) including a side opening and a plurality of members (38 or 106) moveably engaged to the stent wall (Figs. 7-10 & 13a-13f, col. 8 to col. 10, also see the detail description for the materials of the stent as claimed).

In regard to claims 37-38, the claims are product-by-process claims wherein the apparatus is not limited by the steps of a process (See MPEP 2113).

The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Vardi et al.'s system which is capable of being used as claimed if one desires to do so.

10. Claims 17-19, 21, 35-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Zedler et al. (6,494,905). Zedler et al. disclose a single balloon catheter having two balloon portions, a stent body having first and second portions and a plurality of members (13, 14, fig. 2 and col. 5 to col. 6) moveably engaged to the stent wall.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 17-19, 21, 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (6,325,826) in view of Wilson et al. (6,165,195). Vardi et al. disclose all the limitations as claimed except the system for deploying the stent assembly including a first and second catheter instead of only one catheter for deploying the whole stent assembly. Wilson et al. disclose a single catheter with a single balloon for delivering a bifurcated stent assembly. Therefore, it would have been obvious matter of design choice to use only one balloon catheter or two balloon catheters to delivery the bifurcated stent assembly of Vardi et al., since applicant has not disclosed that having a single balloon catheter for delivering the bifurcated stent assembly solves any stated problem or is for any particular purpose and it appears that using two balloon catheters or only one balloon catheter for delivering the bifurcated stent assembly would make the same result.

Response to Arguments

13. Applicant's arguments filed 8/03/04 have been fully considered but they do not place the application in condition for allowance (see rejection above). Applicant argues

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that in contrast to Vardi reference, the claims direct to a single catheter with a single balloon. Examiner disagrees. First, the instant application fails to disclose a system including only a single balloon having only a single balloon (see the 35 USC 112 rejection above). Secondly, the system does not comprise only a single catheter having only a single balloon, the system also comprises a stent body portion disposed on a stent-retaining region as claimed in the claims. Applicant argues that Vardi does not have a single balloon, stent body, and plurality of members such that the stent body is "expanded by the expansion of the single balloon," the plurality of members thereby "extended radially outward from the first stent body to form a scaffold." Examiner disagrees respect to the claimed invention. Vardi discloses a single balloon (402) for expanding a stent body (100) having a plurality of members (106) wherein in the expanded state the plurality of member (102) being extended radially outward from the first stent body to form a scaffold (see figs. 13g-h).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

October 19, 2004


ANHTUAN T. NGUYEN
PRIMARY EXAMINER

10/25/04